We claim:

1. A method for obtaining optimized EPO dosage regimens for a desired pharmacodynamic response in a patient comprising the steps of:

(a) choosing one or more EPO dosage regimens;

(b) using a pharmacokinetic/pharmacodynamic model to determine the pharmacodynamic profile of said one or more EPO dosage regimens; and

(c) selecting said one or more EPO dosage regimens that provide said desired pharmacodynamic response based on said pharmacodynamic profile.

2. The method of claim 1, wherein said pharmacodynamic response comprises of one or more of the group consisting of reticulocyte number, RBC number, and hemoglobin level.

3. The method of claim 1, wherein said patient is anemic.

4. The method of claim 3, wherein said anemia comprises EPO concentration related anemia.

5. The method of claim 4, wherein said anemia comprises end-stage renal or renal failure related anemia.

6. The method of claim 4, wherein said anemia comprises cancer chemotherapy related anemia.

7. The method of claim 4, wherein said anemia comprises AIDS drug therapy related anemia.

8. The method of claim 4, wherein said anemia comprises drug related anemia.

9. The method of claim 8, wherein said drug include cisplatin and zidovudine.

10. The method of claim 1, wherein said patient is undergoing autologous transfusion prior to surgery.

11. The method of claim 1, wherein said patient is recovering from allogenic bone marrow transplant.

12. The method of claim 1, wherein said patient is afflicted with rheumatoid arthritis.

13. The method of claim 1, wherein said dosage regimens are subcutaneous dosage regimens.

14. A method for obtaining optimized EPO dosage regimens for a desired pharmacodynamic response in a patient comprising the steps of:

(a) selecting one or more desired pharmacodynamic responses;

(b) using a pharmacokinetic /pharmacodynamic model to determine EPO dosage regimens that provides said desired one or more pharmacodynamic responses; and

(c) selecting the one or more EPO dosage regimens that provide said desired pharmacodynamic responses.

15. The method of claim 14, wherein said pharmacodynamic response comprises of one or more of the group consisting of reticulocyte number, RBC number, and hemoglobin level.

16. The method of claim 14, wherein said patient is anemic.

17. The method of claim 16, wherein said anemia comprises EPO concentration related anemia.

18. The method of claim 17, wherein said anemia comprises end-stage renal or renal failure related anemia.

19. The method of claim 17, wherein said anemia comprises cancer chemotherapy related anemia.

20. The method of claim 17, wherein said anemia comprises AIDS drug therapy related anemia.

21. The method of claim 17, wherein said anemia comprises drug related anemia.

22. The method of claim 21, wherein said drug include cisplatin and zidovudine.

23. The method of claim 14, wherein said patient is undergoing autologous transfusion prior to surgery.

24. The method of claim 14, wherein said patient is recovering from allogenic bone marrow transplant.

25. The method of claim 14, wherein said patient is afflicted with rheumatoid arthritis.

26. The method of claim 14, wherein said dosage regimens are subcutaneous dosage regimens.

27. A system for selecting an optimal EPO dosage regimens for a patient using a pharmacokinetic/pharmacodynamic model comprising:

(a) a processor that is controlled in accordance with a set of program instructions that determine the steps implemented by said pharmacokinetic/pharmacodynamic model;

(b) a memory coupled to said processor, said memory storing the set of program instructions and parameters used by said pharmacokinetic/pharmacodynamic model; and

(c) a user interface, coupled to said processor, said user interface enabling a user to input parameters used by said pharmacokinetic/pharmacodynamic model.

28. The method of claim 27, wherein said pharmacodynamic response comprises of one or more of the group consisting of reticulocyte number, RBC number, and hemoglobin level.

29. The method of claim 27, wherein said patient is anemic.

30. The method of claim 29, wherein said anemia comprises EPO concentration related anemia.

31. The method of claim 30, wherein said anemia comprises end-stage renal or renal failure related anemia.

32. The method of claim 30, wherein said anemia comprises cancer chemotherapy related anemia.

33. The method of claim 30, wherein said anemia comprises AIDS drug therapy related anemia.

34. The method of claim 30, wherein said anemia comprises drug related anemia.

35. The method of claim 34, wherein said drug include cisplatin and zidovudine.

36. The method of claim 27, wherein said patient is undergoing autologous transfusion prior to surgery.

37. The method of claim 27, wherein said patient is recovering from allogenic bone marrow transplant.

38. The method of claim 27, wherein said patient is afflicted with rheumatoid arthritis.

39. The method of claim 27, wherein said dosage regimens are subcutaneous dosage regimens.

40. A computer program for obtaining optimized EPO dosage regimens for a desired pharmacodynamic response in a patient comprising:

(a) computer code that describes a pharmacokinetic /pharmacodynamic model for EPO, said code providing for selection of one or more desired pharmacodynamic responses and the use of said pharmacokinetic /pharmacodynamic model to determine one or more EPO dosage regimens that provide said desired one or more pharmacodynamic responses; and

(b) computer readable medium that stores said computer code.

41. The method of claim 40, wherein said pharmacodynamic response comprises of one or more of the group consisting of reticulocyte number, RBC number, and hemoglobin level.

42. The method of claim 40, wherein said patient is anemic.

43. The method of claim 42, wherein said anemia comprises EPO concentration related anemia.

44. The method of claim 43, wherein said anemia comprises end-stage renal or renal failure related anemia.

45. The method of claim 43, wherein said anemia comprises cancer chemotherapy related anemia.

46. The method of claim 43, wherein said anemia comprises AIDS drug therapy related anemia.

47. The method of claim 43, wherein said anemia comprises drug related anemia.

48. The method of claim 47, wherein said drug include cisplatin and zidovudine.

49. The method of claim 40, wherein said patient is undergoing autologous transfusion prior to surgery.

50. The method of claim 40, wherein said patient is recovering from allogenic bone marrow transplant.

51. The method of claim 40, wherein said patient is afflicted with rheumatoid arthritis.

52. The method of claim 40, wherein said dosage regimens are subcutaneous dosage regimens.

53. A computer program for obtaining optimized EPO dosage regimens for a desired pharmacodynamic response in a patient comprising:

(a) computer code that describes a pharmacokinetic /pharmacodynamic model for EPO, said code providing for user selection of one or more EPO dosage regimens and the use of said pharmacokinetic /pharmacodynamic model to determine a pharmacodynamic response for said one or more rHuEPO dosage regimens; and

(b) computer readable medium that stores said computer code.

54. The method of claim 53, wherein said pharmacodynamic response comprises of one or more of the group consisting of reticulocyte number, RBC number, and hemoglobin level.

55. The method of claim 53, wherein said patient is anemic.

56. The method of claim 55, wherein said anemia comprises EPO concentration related anemia.

57. The method of claim 56, wherein said anemia comprises end-stage renal or renal failure related anemia.

58. The method of claim 56, wherein said anemia comprises cancer chemotherapy related anemia.

59. The method of claim 56, wherein said anemia comprises AIDS drug therapy related anemia.

60. The method of claim 56, wherein said anemia comprises drug related anemia.

61. The method of claim 60, wherein said drug include cisplatin and zidovudine.

62. The method of claim 53, wherein said patient is undergoing autologous transfusion prior to surgery.

63. The method of claim 53, wherein said patient is recovering from allogenic bone marrow transplant.

64. The method of claim 53, wherein said patient is afflicted with rheumatoid arthritis.

65. The method of claim 53, wherein said dosage regimens are subcutaneous dosage regimens.

66. A method for obtaining optimized EPO dosage regimens for a desired pharmacokinetic response in a patient comprising the steps of:

(a) choosing one or more EPO dosage regimens;

(b) using a pharmacokinetic /pharmacodynamic model to determine the pharmacokinetic profile of said one or more EPO dosage regimens; and

(c) selecting the one or more EPO dosage regimens that provide said desired pharmacokinetic response based on said pharmacokinetic profile.

67. The method of claim 66, wherein said pharmacokinetic response comprises of one or more of the group consisting of serum EPO levels, bioavailablity, and threshold level.

68. The method of claim 66, wherein said patient is anemic.

69. The method of claim 68, wherein said anemia comprises EPO concentration related anemia.

70. The method of claim 69, wherein said anemia comprises end-stage renal or renal failure related anemia.

71. The method of claim 69, wherein said anemia comprises cancer chemotherapy related anemia.

72. The method of claim 69, wherein said anemia comprises AIDS drug therapy related anemia.

73. The method of claim 69, wherein said anemia comprises drug related anemia.

74. The method of claim 73, wherein said drug include cisplatin and zidovudine.

75. The method of claim 66, wherein said patient is undergoing autologous transfusion prior to surgery.

76. The method of claim 66, wherein said patient is recovering from allogenic bone marrow transplant.

77. The method of claim 66, wherein said patient is afflicted with rheumatoid arthritis.

78. The method of claim 66, wherein said dosage regimens are subcutaneous dosage regimens.

79. A method for obtaining optimized EPO dosage regimens for a desired pharmacokinetic response in a patient comprising the steps of:

(a) selecting one or more desired pharmacokinetic responses;

(b) using a pharmacokinetic/pharmacodynamic model to determine EPO dosage regimens that provide said desired one or more pharmacokinetic responses; and

(c) selecting one or more EPO dosage regimens that provide said desired pharmacokinetic responses.

80. The method of claim 79, wherein said pharmacokinetic response comprises of one or more of the group consisting of serum EPO levels, bioavailability, and threshold level.

81. The method of claim 79, wherein said patient is anemic.

82. The method of claim 81, wherein said anemia comprises EPO concentration related anemia.

83. The method of claim 82, wherein said anemia comprises end-stage renal or renal failure related anemia.

84. The method of claim 82, wherein said anemia comprises cancer chemotherapy related anemia.

85. The method of claim 82, wherein said anemia comprises AIDS drug therapy related anemia.

86. The method of claim 82, wherein said anemia comprises drug related anemia.

87. The method of claim 86, wherein said drug include cisplatin and zidovudine.

88. The method of claim 79, wherein said patient is undergoing autologous transfusion prior to surgery.

89. The method of claim 79, wherein said patient is recovering from allogenic bone marrow transplant.

90. The method of claim 79, wherein said patient is afflicted with rheumatoid arthritis.

91. The method of claim 79, wherein said dosage regimens are subcutaneous dosage regimens.

92. A computer program for obtaining optimized EPO dosage regimens for a desired pharmacokinetic response in a patient comprising:

(a) computer code that describes a pharmacokinetic/pharmacodynamic model for EPO, said code providing for selection of one or more desired pharmacokinetic responses and the use of said pharmacokinetic/pharmacodynamic model to determine one or more EPO dosage regimens that provide said desired one or more pharmacokinetic responses; and

(b) computer readable medium that stores said computer code.

93. The method of claim 92, wherein said pharmacokinetic response comprises of one or more of the group consisting of serum EPO levels, bioavailability, and threshold level.

94. The method of claim 92, wherein said patient is anemic.

95. The method of claim 94, wherein said anemia comprises EPO concentration related anemia.

96. The method of claim 95, wherein said anemia comprises end-stage renal or renal failure related anemia.

97. The method of claim 95, wherein said anemia comprises cancer chemotherapy related anemia.

98. The method of claim 95, wherein said anemia comprises AIDS drug therapy related anemia.

99. The method of claim 95, wherein said anemia comprises drug related anemia.

100. The method of claim 99, wherein said drug include cisplatin and zidovudine.

101. The method of claim 92, wherein said patient is undergoing autologous transfusion prior to surgery.

102. The method of claim 92, wherein said patient is recovering from allogenic bone marrow transplant.

103. The method of claim 92, wherein said patient is afflicted with rheumatoid arthritis.

104. The method of claim 92, wherein said dosage regimens are subcutaneous dosage regimens.

105. A computer program for obtaining optimized EPO dosage regimens for a desired pharmacokinetic response in a patient comprising:

(a) computer code that describes a pharmacokinetic/pharmacodynamic model for EPO, said code providing for user selection of one or more EPO dosage regimens and the use of said pharmacokinetic/pharmacodynamic model to determine a pharmacokinetic response for said one or more EPO dosage regimens; and

(b) computer readable medium that stores said computer code.

106. The method of claim 105, wherein said pharmacokinetic response comprises of one or more of the group consisting of serum EPO levels, bioavailability, and threshold level.

107. The method of claim 105, wherein said patient is anemic.

108. The method of claim 107, wherein said anemia comprises EPO concentration related anemia.

109. The method of claim 108, wherein said anemia comprises end-stage renal or renal failure related anemia.

110. The method of claim 108, wherein said anemia comprises cancer chemotherapy related anemia.

111. The method of claim 108, wherein said anemia comprises AIDS drug therapy related anemia.

112. The method of claim 108, wherein said anemia comprises drug related anemia.

113. The method of claim 112, wherein said drug include cisplatin and zidovudine.

114. The method of claim 105, wherein said patient is undergoing autologous transfusion prior to surgery.

115. The method of claim 105, wherein said patient is recovering from allogenic bone marrow transplant.

116. The method of claim 105, wherein said patient is afflicted with rheumatoid arthritis.

117. The method of claim 105, wherein said dosage regimens are subcutaneous dosage regimens.

118. A method for creating a pharmacokinetic model for subcutaneous EPO administration in patients comprising the steps of:

(a) obtaining pharmacokinetic data from patients;
(b) choosing an equation based on said data; and
(c) fitting said pharmacokinetic data to said equation.

119. A method for creating a pharmacodynamic model for subcutaneous EPO administration in patients comprising the steps of:

(a) normalizing serum EPO concentrations;
(b) obtaining pharmacodynamic data;
(c) choosing a pharmacodynamic model;
(d) obtaining equation based on said model; and
(e) fitting pharmacodynamic data to said equation.

120. The method of claim 118, wherein said obtaining pharmacokinetic data comprises:

(a) normalizing serum EPO concentration values from said pharmacokinetic data; and
(b) creating serum EPO versus time profiles based on said normalized data.

121. The method of claim 120, wherein said normalizing step comprises:

(a) obtaining baseline serum EPO concentration values from said pharmacokinetic data by averaging predose serum EPO concentration values at plurality of time points;

(b) obtaining serum EPO concentration values following subcutaneous EPO administration;

(c) obtaining normalized serum EPO concentration values by subtracting predose EPO concentration values from serum EPO concentration values; and

(d) calculating mean normalized serum EPO concentration values at each time point.

122. The method of claim 118, wherein said pharmacokinetic equation comprises the Michaelis-Menten equation.

123. The method of claim 118, wherein said fitting step comprises obtaining estimates of pharmacokinetic parameters utilizing least-squares by Maximum Likelihood method and extended least squares model.

124. The method of claim 123, wherein said parameters are selected from the group consisting of Vmax, Km, Vd, Ka, Fr, $\tau$ (lower doses), and $\tau$ (higher dose).

125. The method of claim 123, wherein said fitting step comprises utilizing ADAPT II software.

126. A method for calculating the bioavailability of EPO following subcutaneous administration comprises the steps of:

(a) obtaining pharmacokinetic data;

(b) calculating AUC;

(c) normalizing AUC to dose; and

(d) deriving an equation to represent said bioavailability of EPO by performing a linear regression of said pharmacokinetic data.

127. The method of claim 119, wherein said normalizing step comprises:

(a) obtaining baseline serum EPO concentration ($C_{bs}$) for each dose group by averaging predose serum EPO concentration values at plurality of time points for each dose group; and

(b) adjusting $C_{bs}$ by adding $C_{bs}$ to serum EPO concentration predicted by

pharmacokinetic model wherein said adjusted $C_{bs}$ may be used as a forcing function for pharmacodynamic analysis.

128. The method of claim 119, wherein said obtaining pharmacodynamic data step comprises:

(a) determining mean predose precursor cell number;
(b) determining mean predose reticolucyte number;
(c) determining mean predose RBC number;
(d) determining mean predose hemoglobin concentration;
(e) obtaining mean reticulocyte versus time profiles according to EPO dose;
(f) obtaining mean RBC versus time profiles according to EPO dose; and
(g) obtaining mean hemoglobin versus time profiles according to EPO dose.

129. The method of claim 119, wherein said pharmacodynamic model comprises a cell production and cell loss model.

130. The method of claim 119, wherein said fitting step comprises obtaining parameters utilizing least squares by Maximum Likelihood method and extended least squares model.

131. The method of claim 130, wherein said parameters comprise estimated parameters and fixed parameters.

132. The method of claim 131, wherein said estimated parameters comprise Ks, $SC_{50}$, and TP.

133. The method of claim 131, wherein said fixed parameters comprise $R_L$, $RBC_L$, Hb, and threshold.

134. The method of claim 130, wherein said fitting step comprises utilizing ADAPT II software.

135. A method for predicting a pharmacodynamic response in a patient to subcutaneous EPO administration comprising the steps of:

(a) selecting EPO dose and dosage regimens; and

(b) determining said pharmacodynamic response based on said dose and dosage regimens.

136. The method of claim 135, wherein said pharmacodynamic response comprises of one or more of the group consisting of reticulocyte number, RBC number, and hemoglobin level.

137. The method of claim 135, wherein said patient is anemic.

138. The method of claim 137, wherein said anemia comprises EPO concentration related anemia.

139. The method of claim 138, wherein said anemia comprises end-stage renal or renal failure related anemia.

140. The method of claim 138, wherein said anemia comprises cancer chemotherapy related anemia.

141. The method of claim 138, wherein said anemia comprises AIDS drug therapy related anemia.

142. The method of claim 138, wherein said anemia comprises drug related anemia.

143. The method of claim 142, wherein said drug include cisplatin and zidovudine.

144. The method of claim 135, wherein said patient is undergoing autologous transfusion prior to surgery.

145. The method of claim 135, wherein said patient is recovering from allogenic bone marrow transplant.

146. The method of claim 135, wherein said patient is afflicted with rheumatoid arthritis.

147. The method of claim 135, wherein said dosage regimens are subcutaneous dosage regimens.

148. A method for administering EPO comprising the steps of:

choosing one or more EPO dosage regimens

using a pharmacokinetic/pharmacodynamic model to determine the pharmacodynamic profile of said one or more EPO regimens;

selecting said EPO dosage regimens that provides a desired pharmacodynamic response based on said pharmacodynamic profile; and

administering said EPO dosage regimen to a patient.

149. The method of claim 148, wherein said EPO dosing regimen comprises administering EPO once a week.

150. The method of claim 148, wherein said EPO dosing regimen comprises administering EPO twice a week.

151. The method of claim 148, wherein said patient is anemic.

152. The method of claim 151, wherein said anemia comprises EPO concentration related anemia.

153. The method of claim 151, wherein said anemia comprises end-stage renal or renal failure related anemia.

154. The method of claim 151, wherein said anemia comprises cancer chemotherapy related anemia.

155. The method of claim 151, wherein said anemia comprises AIDS drug therapy related anemia.

156. The method of claim 151, wherein said anemia comprises drug related anemia.

157. The method of claim 156, wherein said drug is selected from the group consisting of cisplatin and zidovudine.

158. The method of claim 148, wherein said patient is undergoing autologous transfusion prior to surgery.

159. The method of claim 148, wherein said patient is recovering from allogenic bone marrow transplant.

160. The method of claim 148, wherein said patient is afflicted with rheumatoid arthritis.

161. The method of claim 148, wherein said EPO dosage regimens are administered subcutaneously.

162. A method of administering EPO comprising the steps of:

selecting one or more desired pharmacodynamic responses;

using a pharmacokinetic/pharmacodynamic model to determine EPO dosage regimen that provides said desired one or more pharmacodynamic responses;

selecting said one ore more EPO dosage regimens that provides said desired pharmacodynamic responses; and

administering said selected EPO dosage regiment to a patient.

163. The method of claim 162, wherein said EPO dosage regimen comprises administering EPO once a week.

164. The method of claim 162, wherein said EPO dosage regiment comprises administering EPO once every weeks.

165. The method of claim 162, wherein said pharmacodynamic responses are selected from the groups consisting of reticulocyte number, RBC number, and hemoglobin level.

166. The method of claim 162, wherein said patient is anemic.

167. The method of claim 162, wherein said anemia comprises EPO concentration related anemia.

168. The method of claim 162, wherein said anemia comprises end-stage renal or renal failure related anemia.

169. The method of claim 162, wherein said anemia comprises cancer chemotherapy related anemia.

170. The method of claim 162, wherein said anemia comprises AIDS drug therapy related anemia.

171. The method of claim 162, wherein said anemia comprises drug related anemia.

172. The method of claim 171, wherein said drug is selected from the group consisting of cisplatin and zidovudine.

173. The method of claim 162, wherein said patient is undergoing autologous transfusion prior to surgery.

174. The method of claim 162, wherein said patient is recovering from allogenic bone marrow transplant.

175. The method of claim 162, wherein said patient is afflicted with rheumatoid arthritis.

176. The method of claim 162, wherein said EPO dosage regimens are administered subcutaneously.

177. A method for administering EPO to a patient comprising the step of:

administering said EPO on a once-weekly basis.

178. The method of claim 177, wherein said administering comprises a dose 40,000 IU of said EPO.

179. A method for administering EPO to a patient comprising the step of:

administering said EPO on a once every two week basis.

180. The method of claim 179, wherein said administering comprises a dose selected from the group consisting of 80,000 IU/kg, 100,000 IU/kg, and 120,000 IU/kg.

181. A method for enhancing the production of mature red blood cells from young red blood cells in a patient comprising the step of: administering EPO to said patient so that said young red blood cells are induced to become mature red blood cells.

182. A method for maintaining an enhanced level of red blood cells in a patient comprising the step of:

administering a first dose of EPO followed by a second dose of EPO to said patient, wherein said second dose of EPO is administered to said patient at a time after said first dose that coincides with the production of reticulocytes resulting from said first dose of EPO.

183. The method of claim 182, wherein said second dose of EPO is administered to said patient between six and twelve days after said first dose.

184. The method of claim 182, wherein said second dose of EPO is administered to said patient between six and ten days after said first dose.

185. The method of claim 182, wherein said second dose of EPO is administered to said patient seven days after said first dose.

186. A business method comprising the step of:

providing to a consumer an EPO dosing regimen that is a first dose of EPO followed by a second dose of EPO to a patient, wherein said second dose of EPO is administered to said patient at a time after said first dose that coincides with the production of reticulocytes resulting from said first dose of EPO.

187. The method of claim 186, wherein said EPO dose regimen comprises dosing one time per week with an effective amount of EPO.

188. The method of claim 187, wherein said effective amount of EPO comprises 40,000 IU/kg.

189. The method of claim 186, wherein said EPO dose regimen comprises dosing once every two weeks with an effective amount of EPO.

190. The method of claim 189, wherein said effective amount of EPO is selected from the group consisting of 80,000 IU/kg, 100,000 IU/kg, and 120,000 IU/kg.

191. A business method comprising the step of:

providing to a patient an EPO dosing regimen that is a first dose of EPO followed by a second dose of EPO to a patient, wherein said second dose of EPO is

administered to said patient at a time after said first dose that coincides with the production of reticulocytes resulting from said first dose of EPO.

192. The method of claim 191, wherein said EPO dose regimen comprises dosing one time per week with an effective amount of EPO.

193. The method of claim 192, wherein said effective amount of EPO comprises 40,000 IU/kg.

194. The method of claim 191, wherein said EPO dose regimen comprises dosing once every two weeks with an effective amount of EPO.

195. The method of claim 194, wherein said effective amount of EPO is selected from the group consisting of 80,000 IU/kg, 100,000 IU/kg, and 120,000 IU/kg.

196. A business method comprising the step of:

providing a dosing regimen of EPO to a user or patient.

197. The method of claim 196, wherein said dosing regimen is once weekly.

198. The method of claim 196, wherein said dosing regimen is once every two weeks.

199. The method of claim 196 further comprising the step of:

providing EPO in conjunction with said providing a dosing regimen of EPO to a user or patient.

200. The method of claim 196, wherein said providing step comprises selling.

201. The method of claim 199, wherein said providing step comprises selling.

202. The method of claim 196, wherein said providing step is performed through the use of a computer system.

203. The method of claim 199, wherein said providing step is performed through the use of a computer system.